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EXAMINER

TUNG, P

ART UNIT

1652

PAPER NUMBER

13

DATE MAILED: 03/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademark

Office Action Summary

Application No.

09/407,806

Applicant(s)

Murphy et al.

Examiner

Peter Tung

Group Art Unit

1652



☒ Responsive to communication(s) filed on Jan 2, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-14 and 17-23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-14 and 17-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Claims 1-14 and 17-23 are pending.
2. Claims 10-12 are withdrawn from further consideration as being drawn to a non-elected invention.

Claim Objections

3. Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The DNA encoding a polypeptide can only be either single stranded or double stranded.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14 and 19, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide which encodes SEQ ID NO: 4 or is 70-90% identical in sequence to a polynucleotide which encodes SEQ ID NO: 4 and where said polynucleotide encodes a polypeptide having alpha galactosidase activity, does not reasonably

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provide enablement for a polynucleotide which is at least 70% identical to a polynucleotide encoding an enzyme comprising SEQ ID NO: 4 and encodes a protein having enzymatic activity or which has 90% identity under stringent conditions to a polynucleotide encoding SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the relative skill of those in the art, (6) the predictability or unpredictability of the art, and (7) the breadth of the claims. The breadth of the claims encompass any polynucleotide which is at least 70% identical to said polynucleotide and encodes a protein having enzymatic activity. Insufficient guidance and insufficient examples have been provided on those polynucleotides which are 70% identical to said polynucleotides and which encode a protein which is not an alpha galactosidase. Insufficient guidance and insufficient examples have been provided on those polynucleotides which are 90% identical under stringent conditions to said polynucleotides and which encode a protein which is not an an alpha galactosidase. The skill of those in the art is low in making said polynucleotides which encode a protein which is not an alpha galactosidase. There is unpredictability in making a protein with another enzymatic activity absent any guidance or examples. Undue experimentation would be

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required to enable the full scope of the claims based upon the limiting scope of the disclosure.

This rejection may be overcome by replacing enzymatic activity with “alpha galactosidase activity” in claim 13 and deleting “under stringent conditions” in claim 14

6. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is explained in the previous Office action.

7. Applicants argue that genomic DNA encoding an enzyme of the present invention could easily be obtained. Applicants further argue that genomic sequences of bacteria do not have exon/intron regions and therefore the claimed invention properly describes the complete structure of a genomic DNA of the instant invention.

8. Applicant's arguments filed 1/2/01 have been fully considered but they are not persuasive. The basis of the rejection is based upon adequate written description. The genomic DNA claimed has not been described in the instant specification. While exon/intron regions are not present, the disclosed DNA only teaches the coding sequence for an alpha galactosidase and does not provide regulatory, promoter and terminator sequences that precede and follow the coding sequence, which would be present in genomic DNA.

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Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-9 and 13, 14 and 17-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-14 of U.S. Patent No. 5,958,751. This rejection is explained in the previous Office action.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


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